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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,711	02/17/2006	Hidegori Urata	Q93208	4660
23373 7590 02/27/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
PURDY, KYLE A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/568,711

Applicant(s)

URATA ET AL.

Examiner

Kyle Purdy

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/IS/CI)
Paper No(s)/Mail Date 2 pages (05/22/2008 and 11/24/2008)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 11/24/2008 wherein claims 1 and 2 have been amended and claims 3-39 have been cancelled.

2. Claims 1 and 2 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 11/24/2008 regarding the objection of claims 17 made by the Examiner have been fully considered and they are found persuasive. This objection is withdrawn by cancellation of the claim.

4. Applicants arguments filed 11/24/2008 regarding the rejection of claims 1-5 and 7-16 made by the Examiner under 35 USC 112, second paragraph have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claims. Note, claims 3-5 and 7-16 have been cancelled.

5. Applicants arguments filed 11/24/2008 regarding the rejection of claims 2-4 and 8-16 made by the Examiner under 35 USC 112, first paragraph (enablement) have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claims. Note, claims 3, 4 and 8-16 have been cancelled.

6. Applicants arguments filed 11/24/2008 regarding the rejection of claims 3-6 and 7-16 made by the Examiner under 35 USC 103(a) over Nishimura et al. (US 6410576) in view of Tsuchiya et al. (EP 1249450), Imura et al. (AJH, 1995), Ishihara et al. (WO 01/12226) and

Nishimura et al. (WO 01/32621) have been fully considered and they are found persuasive. This rejection has been overcome by cancellation of the claims.

7. Applicants arguments filed 11/24/2008 regarding the rejection of claims 1 and 2 made by the Examiner under 35 USC 103(a) over Nishimura et al. (US 6410576) in view of Tsuchiya et al. (EP 1249450), Iimura et al. (AJH, 1995), Ishihara et al. (WO 01/12226) and Nishimura et al. (WO 01/32621) have been fully considered but they are not found persuasive.

8. The rejection of claims 1 and 2 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 05/23/2008.

9. In regards to the 103(a) rejection, Applicant asserts the following:

A) The Examiner used improper hindsight because the references do not teach a relationship between chymase and glucose metabolism. Applicant indicates the Examiner does not teach that chymase is involved in glucose metabolism. Additionally, Applicant indicates that there are many drugs which are used to treat symptoms of disease rather than the underlying cause.

10. In response to A, it's unclear how the Examiner used hindsight in the applied rejection. The primary reference to Nishimura indicates that chymase inhibition is useful for treating diabetes complications. As complications of diabetes include impaired glucose tolerance, it would readily occur to a person of ordinary skill that by treating diabetes with or without a chymase inhibitor would necessarily treat the patient's ability to tolerate blood glucose. Treating the disease (diabetes) would necessarily treat the symptom (glucose intolerance). Therefore, any person of ordinary skill would have sufficiently motivated to look to the art for chymase inhibitors such as the instantly claimed compound and use it in a method for the treatment of diabetes. If the result was that it improved the condition by improving the subject's ability to

tolerate glucose, then that would have been a product of ordinary skill and common sense, not a product of improper hindsight. Applicant also argues that drugs often treat symptoms of disease, not the underlying cause. This argument is not found persuasive. As discussed above, diabetes is a disease which is characterized by multiple symptoms, one being glucose intolerance. Thus, by treating diabetes with a drug, that very treatment would necessarily treat the symptoms of said condition including glucose intolerance.

Maintained Rejections, of Record
Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(c), (f) or (g) prior art under 35 U.S.C. 103(a).

13. **Claims 1-6 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al. (US Patent 6,410,576) in view of all Tsuchiya et al. (European Patent**

Application EP 1 249 450), Iimura et al. ("Effects of Angiotensin Receptor Antagonist and Angiotensin Converting Enzyme Inhibitor on Insulin Sensitivity in Fructose-Fed Hypertensive Rats and Essential Hypertensives," 1995, AJH, Volume 8, Pages 353-357 and cited by Applicant), Ishihara et al. (WIPO Document WO01/12226 and cited by Applicant) and Nishimura et al. (WIPO Document WO 01/32621 and cited by Applicant, hereinafter **Nishimura1).**

14. Nishimura et al. teach that compounds that exhibit chymase inhibitory activity are expected to be effective at treating diabetes complications (columns 9, line 62 to column 10, line 17). Chymase inhibitor compounds are expected to be useful as drugs, particularly to be effective in treating various diseases originating from chymase such as diabetes complications (column 52, lines 17-22).

15. Nishimura et al. does not teach the specific diabetes complications or the underlying mechanism creating the complications. In addition, Nishimura et al. does not identify 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid as a chymase inhibitor.

16. Tsuchiya et al. teach benzimidazole derivatives as an inhibiting agent against human chymase activity is clinically applicable as a treating agent for various diseases associated with human chymase (page 2, paragraphs 1 and 7 and page 67, paragraph 238). Tsuchiya et al. teach that the benzimidazole derivatives have an extremely high chymase inhibitor activity and that one such disclosed derivative is 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid (page 2, paragraph 5 and Page 8, compound 56 and Example 15, page 64).

17. Iimura et al. teach an ACE inhibitor improves insulin-resistant glucose uptake (insulin sensitivity) in the insulin-resistant hypertensive rat model and essential hypertensives (Abstract).

18. Ishihara et al. teach that compounds having a chymase inhibitory effect are expected to be a treatment of diseases such as diabetic retinopathy (Abstract).

19. Nishimura¹ teaches chymase compounds that exhibit excellent inhibitory activity are useful as therapeutic drugs to treat complications of diabetes and obesity (Abstract).

20. It would have been obvious to one of ordinary skill in the art at the time of the invention, that if chymase inhibitors in general were effective at treating complications of diabetes as disclosed by Nishimura et al. and one had a compound such as 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2-ylthio)butanoic acid which is taught by Tsuchiya et al. as having extremely high chymase inhibitor activity, the compound taught by Tsuchiya et al. would also treat diabetes complications such as glucose intolerance.

21. It would have been obvious to one of ordinary skill in the art at the time of the invention, that in treating the complications associated with diabetes, one would also inherently treat the underlying cause of diabetes which would be the insulin resistance and associated glucose intolerance. See MPEP 2112.01 II, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), and, as such, it would be expected that a compound that treated diabetes complications would have to treat the underlying cause of diabetes, like glucose intolerance. Therefore, absent evidence to the contrary from Applicant, the method taught by Nishimura et al. in view of Tsuchiya et al. and that disclosed by Applicant will possess the same

effect since identical products cannot have mutually exclusive properties. Therefore, Nishimura et al. in view of Tsuchiya et al, renders instant claims 1 and 2 obvious.

22. Therefore, the teachings of Nishimura et al., in view of all Tsuchiya et al., Iimura et al., Ishihara et al. and NishimuraI would render the instant invention obvious.

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/
Examiner, Art Unit 1611
February 19, 2009*

*/David J Blanchard/
Primary Examiner, Art Unit 1643*